



UNITED STATES DEPARTMENT OF COMMERCE
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SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
06/727,105	04/25/85	SCHALLY A	KIRK3.0-001

OMRIM, BEHR
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EDISON, NJ 08837

EXAMINER	
PHILLIPS, D	
ART UNIT	PAPER NUMBER
129	2
DATE MAILED 02/21/86	

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), _____ day(s) from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|---|---|
| 1. <input checked="" type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input type="checkbox"/> Notice re Patent Drawing, PTO-948. |
| 3. <input type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449 | 4. <input type="checkbox"/> Notice of informal Patent Application, Form PTO-152 |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474 | 6. <input type="checkbox"/> _____ |

Part II SUMMARY OF ACTION

1. ☒ Claims 1-21 are pending in the application.
Of the above, claims _____ are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 1-21 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings which are acceptable for examination purposes until such time as allowable subject matter is indicated.
8. ☐ Allowable subject matter having been indicated, formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. These drawings are ☐ acceptable;
☐ not acceptable (see explanation).
10. ☐ The ☐ proposed drawing correction and/or the ☐ proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved. ☐ disapproved (see explanation). However, the Patent and Trademark Office no longer makes drawing changes. It is now applicant's responsibility to ensure that the drawings are corrected. Corrections MUST be effected in accordance with the instructions set forth on the attached letter "INFORMATION ON HOW TO EFFECT DRAWING CHANGES", PTO-1474.
12. ☐ Acknowledgment is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received
☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

Art Unit 123

The specification is objectionable under 35 U.S.C. 101 and 112, first paragraph as indicating that the instant compounds are effective for the treatment of cancer. This is a type of utility that requires additional proof by way of clinical evidence. Applicants must either substantiate this material or delete it from the specification.

Claim 20 is rejected under 35 U.S.C. 112, first paragraph as containing a utility that needs more substantiation. See above discussion.

Claims 18 and 19 are rejected under 35 U.S.C. 112, second paragraph as being incomplete claims in not setting forth the use for the instant composition. In order to be a complete composition claim the use of said composition must be set forth.

Claims 1, 12 and 16-20 are rejected under 35 U.S.C. 112, second paragraph as being indefinite claims. The definitions of C' and C" are confusing since if either C' or C" is Cys, the other one must be Cys. A compound holding its C' is Cys and C" is Lys is not contemplated and cannot exist because the bond cannot be formed easily between these two moieties. Likewise, two Lys moieties in the molecule will not form the cyclic structure. The same holds true for two dicarboxylic amino acids.

Claims 16 and 17 are rejected under 35 U.S.C. 103 as being obvious over the three Sarantakis patents. These patents show the formation of a disulfide bond by oxidation of the two cysteine mercaptans. It is considered

the instant process is but an obvious variation of the process shown in the art. See In re Durden et al., 226 U.S.C.Q. 359.

Claims 1-15 and 19-21 are rejected under 35 U.S.C. 103 as being obvious over the Sarantakis patents (904) and (394). These two patents show larger peptides with the same amino acid contents between the cysteine moieties. They also indicate that activity could be expected by the addition on either end of the cyclic structure of amino acids that are within the scope of the instant claims. It would be obvious to delete X₁ from the (904) patent.

Claims 1-15 and 19-21 are rejected under 35 U.S.C. 103 as being unpatentable in view of the Bauer, et al., patent. This patent generically discloses the claims of this application. The species of the patent would render the instantly claimed species obvious.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Phillips whose telephone number is (703) 557-1094. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 557-3920.

2-15-86:cdc

Delbert R. Phillips

DELBERT R. PHILLIPS
PRIMARY EXAMINER
ART UNIT 123